DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

August 28, 1997

Ref: 97-DAL-WL-41

WARNING LETTER

FEDERAL EXPRESS

Mr. Bill T. Teague
President, Chief Executive Officer and
Responsible Head
Gulf Coast Regional Blood Center
1400 La Concha
Houston, Texas 77054

Dear Mr. Teague:

During an inspection of Gulf Coast Regional Blood Center on July 10 through August 15, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

Failure to maintain and follow adequate written standard operating procedures for the following: [21 CFR 606.100]

a. Roles of the Medical Director, Physician Substitutes and Facility Specialist relating to review of donor records and test results.

b. Equipment quality control and preventative maintenance used for immunoassay, automated blood-typing chemistry assays and apheresis.

c. Quality control on platelets (month of April 1997).

d. Reporting errors and accidents promptly to FDA.

Failure to properly maintain adequate and complete records and changes to quality control records. [21 CFR 606.160]

Failure to always take corrective action and to timely report errors and accidents to FDA which may affect the safety, purity or potency of any product. An examination

of 43 reportable error and accident reports revealed 24 were submitted to the FDA ranging from seven weeks to 13 months, with three reports not being available for the investigator to review. Two error and accident reports did not reveal corrective action. [21 CFR 600.14]

Equipment maintenance records are not adequate and complete for all equipment, including the [redacted] and [redacted]. The lack of proper maintenance on the first four pieces of equipment has been previously cited by FDA. [21 CFR 606.60]

Failure to assure that employees have the necessary training to operate equipment, e.g., in March of 1997 prior to the completion of their training five technicians operated the apheresis equipment and collected from donors with no indication of supervision. [21 CFR 606.20]

The investigator presented a list of observations (FDA-483) to you and your staff at the close of the inspection and a copy is being attached to this letter for your reference. The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as Responsible Head to assure that your establishment is in compliance with all requirements of the federal regulations. Please provide a written response to each observation listed on the FDA-483.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps that you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed. Please address your response to Gwen Gilbreath, Compliance Officer.

Sincerely,

Joseph R. Baca
District Director